

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1-130. (Cancelled)

131. (Cancelled)

132. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is input by said patient.

133. (Cancelled)

134. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is a therapeutic response factor.

135. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is an electrophysiological parameter.

136. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is a three-dimensional data array of electrophysiological parameters.

137. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is a biochemical marker.

138. (Withdrawn) The process as recited in claim 137, wherein said biochemical marker is selected from the group consisting of lactate, C-reactive protein, oxygen, and carbon dioxide.

139. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is blood pressure.

140. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is blood flow velocity.

141. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is cardiac ejection fraction.

142. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is inferred from ultrasonic image data.

143. (Withdrawn) The process as recited in claim 142, wherein said at least one parameter inferred from ultrasonic image data is right ventricle volume.

144. (Withdrawn) The process as recited in claim 142, wherein said at least one parameter inferred from ultrasonic image data is left ventricle volume.

145. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is inferred from magnetic resonance image data.

146. (Withdrawn) The process as recited in claim 145, wherein said at least one parameter inferred from magnetic resonance image data is right ventricle volume.

147. (Withdrawn) The process as recited in claim 145, wherein said at least one parameter inferred from magnetic resonance image data is left ventricle volume.

148. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is a numerical values that quantifies a prior aspect of said patient.

149. (Withdrawn) The process as recited in claim 131, wherein said at least one parameter is predictive parameter of said patient.

150. (Cancelled)

151. (Cancelled)

152. (Cancelled)

153. (Cancelled)

154. (Cancelled)

155. (Cancelled)

156. (Withdrawn) The process as recited in claim 131, wherein said at least one command instruction of said algorithm instructs said direct mechanical ventricular assistance apparatus to provide training to said heart.

157. (Withdrawn) The process as recited in claim 131, wherein said at least one command instruction of said algorithm instructs said direct mechanical ventricular assistance apparatus to assist in regeneration of said heart.

158. (Cancelled)

159. (Withdrawn) The process as recited in claim 131, wherein said exporting of said at least one command instruction instructs the delivery of a first therapeutic agent.

160. (Withdrawn) The process as recited in claim 159, wherein said first therapeutic agent is selected from the group consisting of anti-inflammatory agents, gene therapy agents, gene transfer agents, stem cells, chemo-attractants, cell regeneration agents, ventricular remodeling agents, anti-infection agents, tumor suppressants, tissue and/or cell engineering agents, imaging contrast agents, tissue staining agents, nutrients, and mixtures thereof.

161. (Withdrawn) The process as recited in claim 131, wherein said exporting of said at least one command instruction instructs the delivery of a first regenerative agent.

162. (Withdrawn) The process as recited in claim 161, wherein said first regenerative agent is selected from the group consisting of tissue scaffold materials, biochemical materials, stem cells, and electrical stimulation.

163-244. (Cancelled)

245. (Currently Amended) A method of treating a patient requiring heart function assistance or therapy comprising:

- 1) connecting the patient to a cardiac assist device, said device comprising:
 - a) a compliant cup conformable to said heart configured to encompass, and to seal and conform to said heart from atrio-ventricular groove to apex throughout systolic and diastolic actuation by imposing negative pressure between said cup and said heart, said cup having ~~an~~ a compliant exterior wall attached to ~~an~~ a compliant interior liner forming a continuous annular cavity between said wall and said liner, wherein the liner comprises a tapered unbonded transition section reducing in thickness to a thin section forming the liner adjacent a liner portion attached to the wall; and
 - b) a drive system in closed fluid communication with said cavity to effect displacement of said cavity;
 - c) a sensor; and
 - d) a control system in communication with said drive system and with said sensor;
- 2) collecting data from said sensor and importing said data into said control system;
- 3) using an algorithm to formulate a command instruction from said control system in response to said data; and

- 4) exporting said command instruction from said controller to said drive system to effect displacement of said annular cavity and wherein said displacement actively supports systolic and diastolic actuation of the heart.

246. (Previously Presented) The method of claim 245, wherein data imported into the control system corresponds to the fluid pressure within said annular cavity.

247 (Previously Presented) The method of claim 245, wherein said command instruction maintains constant cardiac performance.

248. (Previously Presented) The method of claim 245, wherein said sensor detects one or more of: device operational data; anatomical data; hemodynamic data; electrophysiological data; biochemical/biological data; acoustical data; tissue characteristic data; temperature data; optical data; and/or device mechanical data.

249. (Previously Presented) The method of claim 248, further comprising one or more sensors remote to said cup.

250. (Previously Presented) The method of claim 249, wherein one or more sensors is an electrophysiological sensor positioned externally on said patient.

251. (Previously Presented) The method of claim 245, wherein said sensor is used to guide installation of the device and/or to assess cardiac performance under the influence of the device.

252. (Currently Amended) The method of claim 245, wherein a said ~~sensor is used to confirm that the~~ collects data relating to ~~liner is conforming~~ conformation to, and is in contact with, an exterior surface of the heart corresponding to the right and/or left ventricles throughout systolic and diastolic actuation.

253-255. (Canceled)

256. (New) The method of claim 245, wherein said sensor collects data relating to fit of the cup on the heart.

257. (New) The method of claim 245, wherein the compliant exterior wall and compliant interior liner are the same material.

258. (New) The method of claim 257, wherein the wall and liner material is a strain neutral material that retains isotropic or near-isotropic properties after repeated cyclic loadings.

259. (New) The method of claim 257, wherein the wall and liner material is a heat curable liquid silicone rubber.

260. (New) The method of claim 257, wherein the compliant exterior wall has a wall thickness between about 2 millimeters and about 8 millimeters.

261. (New) The method of claim 257, wherein the liner is a rolling diaphragm liner.

262. (New) The method of claim 261, wherein the exterior wall and interior liner are joined through an integral liner and seal assembly.

263. (New) The method of claim 262, wherein the seal of the integral liner and seal assembly is the same material as wall and liner.

264. (New) The method of claim 245, wherein the liner portion attached to the wall is configured to mate with a recess in said wall.

265. (New) A method of treating a patient requiring heart function assistance or therapy comprising:

- 1) connecting the patient to a cardiac assist device, said device comprising:
 - a) a cup having a compliant exterior wall joined to a compliant interior rolling diaphragm liner continuously along two circumferential lines forming a continuous annular cavity between said wall and said liner, said cup configured to encompass, and to seal and conform to said heart from apex to atrio-ventricular groove; and

- b) a drive system in closed fluid communication with said cavity to effect displacement of said cavity;
 - c) a sensor; and
 - d) a control system in communication with said drive system and with said sensor;
- 2) collecting data from said sensor and importing said data into said control system;
 - 3) using an algorithm to formulate a command instruction from said control system in response to said data; and
 - 4) exporting said command instruction from said controller to said drive system to effect displacement of said annular cavity, and wherein said displacement actively supports systolic and diastolic actuation of the heart.

266. (New) The method of claim 265, wherein data imported into the control system corresponds to fluid pressure within said annular cavity.

267. (New) The method of claim 265, wherein said command instruction maintains constant pump function of said heart.

268. (New) The method of claim 265, wherein said sensor detects one or more of: device operational data; anatomical data; hemodynamic data; electrophysiological data; biochemical/biological data; acoustical data; tissue characteristic data; temperature data; optical data; and/or device mechanical data.

269. (New) The method of claim 265, further comprising one or more sensors remote to said cup.

270. (New) The method of claim 269, wherein one or more sensors is an electrophysiological sensor positioned externally on said patient.

271. (New) The method of claim 265, wherein said sensor collects data relating to fit of the cup on the heart.

272. (New) The method of claim 265, wherein said sensor collects data relating to liner conformation and contact with the heart surface throughout systolic and diastolic actuation.

273. (New) The method of claim 265, wherein said sensor collects data relating to pump function of the heart under the influence of the device.

274. (New) The method of claim 265, wherein the exterior wall and interior rolling diaphragm liner are joined through an integral liner and seal assembly.

275. (New) The method of claim 265, wherein the seal is the same material as wall and liner.

276. (New) The method of claim 265, wherein the interior rolling diaphragm liner comprises a tapered unbonded transition section reducing in thickness to a thin

section forming the liner, and said tapered section is adjacent a liner portion attached to the exterior wall.

277. (New) The method of claim 265, wherein the liner portion attached to the exterior wall is configured to fit in a recess within said wall.